510(K) SUMMARY

Submitted by:	Synovis Surgical Innovations 2575 University Avenue West St. Paul, MN 55114-1024 Tel: 651-796-7300 Fax: 651-642-9018
Contact Person:	Fonda Burley At address above
Device Trade Name:	Veritas Collagen Matrix
Common Name:	Surgical Mesh
Classification Name:	Mesh, Surgical 21 CFR 878.3300
Product Code:	FTM, OXE, OXB, OWV, PAJ
Predicate devices:	Veritas Collagen Matrix, K002233
Device Description:	An implantable surgical patch comprised of non-crosslinked bovine pericardium. Veritas Collagen Matrix undergoes proprietary processing that allows neo-collagen formation and neo-vascularization of the implanted device and permits replacement of the device with host tissue, or remodeling.
Statement of Intended use:	Veritas Collagen Matrix is intended for use as an implant for the surgical repair of soft tissue deficiencies, this includes but is not limited to the following: Buttressing and reinforcing staple lines during lung resection (e.g., wedge resection, blebectomy, lobectomy, bullectomy, bronchial resection, segmentectomy, pnuemonectomy/pneumectomy, pneumoreduction) and other incision and excision of the lung and bronchus. Reinforcement of the gastric staple line during the bariatric surgical procedures of gastric bypass and gastric banding. Abdominal and thoracic wall repair, muscle flap reinforcement, rectal prolapse excluding rectocele, reconstruction of the pelvic floor excluding transvaginal organ prolapse repair, and repair of hernias (e.g., diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal, umbilical).

Technological Comparisons:	Veritas Collagen matrix is substantially equivalent to the predicate device, having the same technological characteristics and indications for use.
Technology/Device Testing:	The Veritas Collagen Matrix is substantially equivalent to the predicate device in terms of testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Synovis Surgical Innovations
% Ms. Angela Mallery
Regulatory Affairs Manager
2575 University Avenue West
St. Paul, Minnesota 55114

January 28, 2013

Re: K030879
Veritas® Collagen Matrix
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: OXE, OXB, FTM, OWV, PAJ
Dated: March 18, 2003
Received: March 20, 2003

Dear Ms. Mallery:

This letter corrects our substantially equivalent letter of April 24, 2003.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K030879

Device Name: Veritas Collagen Matrix

Indications For Use:

Veritas Collagen Matrix is intended for use as an implant for the surgical repair of soft tissue deficiencies; this includes but is not limited to the following:

Buttressing and reinforcing staple lines during lung resection (e.g., wedge resection, blebectomy, lobectomy, bullectomy, bronchial resection, segmentectomy, pnuemonectomy/pneumectomy, pneumoreduction) and other incision and excision of the lung and bronchus.

Reinforcement of the gastric staple line during the bariatric surgical procedures of gastric bypass and gastric banding.

Abdominal and thoracic wall repair, muscle flap reinforcement, rectal prolapse excluding rectocele, reconstruction of the pelvic floor excluding transvaginal organ prolapse repair, and repair of hernias (e.g., diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal, umbilical).

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K030879